

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/004260

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 25

because:

☒ the said international application, or the said claims Nos. 25  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 25 relates to a method for treatment of the human body by therapy, which does not require an international preliminary examination in accordance with PCT Rule 39.1 (iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 25

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	3-5, 13, 14, 16, 19-21, 22	YES
	Claims	1, 2, 6-12, 15, 17, 18, 23, 24	NO
Inventive step (IS)	Claims	3-5, 13, 14, 16, 19-21, 22	YES
	Claims	1, 2, 6-12, 15, 17, 18, 23, 24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO
<b>2. Citations and explanations:</b>			
<p>Document 1: WO, 2003/068230, A1 (Pharmacia Corporation), 21 August, 2003 (21.08.03), full text, particularly refer to example 324 and claim 69, &amp; CA, 2476012, A, &amp; US, 2004/058964, A1, &amp; BR, 2003007631, A, &amp; EP, 1490064, A1</p> <p>Document 2: WO, 2001/82925, A1 (Takeda Chemical Industries, Ltd.), 8 November, 2001 (08.11.01), &amp; AU, 200152596, A, &amp; JP, 2002-241274, A &amp; EP, 1285651, A1, &amp; US, 2004/077628, A1</p> <p>Document 3: JP, 2002-003370, A (Takeda Chemical Industries, Ltd.), 9 January, 2002 (09.01.02), &amp; WO, 2001/21577, A2, &amp; EP, 1218336, A2, &amp; AU, 200073157, A</p> <p>Document 4: JP, 2004-504303, A (Shinaputeikku Famasutikaru Corp.), 12 February, 2004 (12.02.04), &amp; WO, 2002/06245, A1, &amp; AU, 200173192, A, &amp; EP, 1299362, A1</p> <p>Document 5: WO, 2001/87834, A1 (Takeda Chemical Industries, Ltd.), 22 November, 2001 (22.11.01), &amp; AU, 200156733, A, &amp; JP, 2002-371059, A, &amp; EP, 1283199, A1, &amp; US, 2003/158177, A1</p> <p>Document 6: WO, 2002/94799, A2 (Neurogen Corporation), 28 November, 2002 (28.11.02), &amp; BR, 200209932, A, &amp; EP, 1389189, A2, &amp; KR, 2004012851, A</p> <p>Document 7: JP, 2004-502423, A (Shinaputeikku Famasutikaru Corp.), 29 January, 2004 (29.01.04), &amp; AU, 200173207, A, &amp; EP, 1246847, A2, &amp; WO, 2002/02744, A2</p> <p>Document 8: WO, 2003/045912, A1 (Warner-Lambert Company LLC), 5 June, 2003 (05.06.03), &amp; US, 2003/162787, A1, &amp; CA, 2468715, A, &amp; BR, 2002014519, A, &amp; EP, 1465864, A1</p> <p>Claims 1, 2, 6-12, 15, 17, 18, 23 and 24  The subject matters of claims 1, 2, 6-12, 15, 17, 18, 23 and 24 do not appear to be novel or to involve an inventive step in view of document 1 cited in the ISR.</p> <p style="padding-left: 40px;">Document 1 describes a pyridone derivative useful as a drug corresponding to the compound described in claims 1, 2, 6-12, 15, 17, 18, 23 and 24 (see example 324 and claim 69).</p> <p>Claims 3-5, 13, 14, 16, 19-21 and 22  The subject matters of claims 3-5, 13, 14, 16, 19-21 and 22 appear to be novel and to involve an inventive step in view of documents 1-8 cited in the ISR.</p>			

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Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

Documents 1 and 8 neither describe nor suggest the compounds described in claims 3-5, 13, 14, 16, 19-21 and 22, and the medicinal action of the compounds is different from that of the compounds described in documents 1 and 8.

Documents 2-7 describe a compound showing a melanin aggregated hormone receptor antagonism, but neither describe nor suggest the compound described in claims 3-5, 13, 14, 16, 19-21 and 22.

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**Box No. VIII      Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The compounds described in claims 1-18 and 22-24 contain a large number of compounds. However, the compounds which are supported by the specification in the sense of PCT Article 6 and which are disclosed in the sense of PCT article 5 are only a few ones described in the claims.

Therefore, in this international preliminary examination report, we have made a report based on the examination performed for the compounds which are concretely disclosed in the specification.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

International Patent Classification (IPC)  
Int.Cl.<sup>7</sup>

A61K31/506, 31/501, A61P5/00, 43/00, 3/04, 3/10, 3/06, 19/06, 1/16, 9/10, 9/04, 9/12,  
13/12, 3/12, 25/24, 25/22, 25/08, 25/28, 25/18, 25/20, 25/14, 27/00, 25/36, 25/32, 15/00,  
1/00, 11/00, 35/00, 17/00, 13/02